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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/553,232 | 10/03/2006 | Mark L. Witten | 12241-021-999 | 2163 |

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| EXAMINER | |
|---|---|
| LUKTON, DAVID | |
| ART UNIT | PAPER NUMBER |
| 1654 | |
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| 12/31/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/553,232 | WITTEN, MARK L. | |
| | Examiner | Art Unit | |
| | DAVID LUKTON | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *3,5 and 7-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 9/15/09, claims 1-3 have been amended.

Claims 1-9 are now pending.

Claims 1, 2, 4, 6 are examined in this Office action; claims 3, 5, 7, 8, 9 are withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites that any of the following can be "altered": Clara cell necrosis, pulmonary alveolar macrophage number, neutrophil number, alveolar capillary barrier membrane damage, 6-keto-PGF-1-*alpha* concentration and PGE-2 concentration. To say that a given concentration can be altered or that the extent of a given biochemical process can be altered means that the concentration or extent can be either increased or decreased. However, descriptive support for both an increase and a decrease is lacking.

Claims 1, 2, 4, 6 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As indicated above, claim 1 now recites that any of the following can be "altered": Clara cell necrosis, pulmonary alveolar macrophage number, neutrophil number, alveolar capillary barrier membrane damage, 6-keto-PGF-1-*alpha* concentration and PGE-2 concentration. Thus, claim 1 is asserting that Clara cell necrosis is exacerbated by administration of the peptide, that the macrophage and neutrophil numbers are increased, and that membrane damage is worsened as a consequence of administering the peptide. Even if one had a reason for worsening the patient's condition (which reason is not apparent), it is not apparent where enablement for such a result might be found.

Claims 1, 2, 4, 6 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As indicated above, the claims now encompass the result of worsening the patient's condition, at least as manifest by the various biochemical parameters listed in claim 1. It

is not apparent how one might be achieving a successful "treatment" if the patient's condition is worsening.

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 2, 4, 6 are rejected under 35 U.S.C. §103 as being unpatentable over Witten (USP 5,998,376).

As indicated previously, Witten teaches that aerosolized substance P can be used to treat disorders resulting from inhalation of jet fuel. Among the relevant passages are the following: col 2, line 65+, col 4, line 59, col 4, line 62, col 5, line 16+. In particular, if substance P is indeed effective to treat viral infections, as asserted by Witten, the immunologist of ordinary skill would expect a gradual reduction in the presence of

inflammatory mediators as the virus is eradicated. Applicant may hold the view that suppression of the immune system is beneficial to those suffering from viral infections. However, this is not the correct view; for a patient stricken with a viral infection, suppression of the immune system can exacerbate the illness.

In response, applicants have argued that the reference doesn't explicitly state that SARS or ARDS can be successfully treated with the peptides disclosed therein. This point is correct. However, Witten does state that substance P will be effective to treat viral infections in general. If this assertion is indeed correct, then a practioner of the Witten invention is more likely to achieve success in the treatment of SARS or ARDS than a practioner of example 1 of the application 10/553232. In the instant application, the test animals were not infected with a virus. Applicants are only speculating that, were the animals to be infected with a virus, some therapeutic benefit might accrue. But no one knows for sure. The assertion that viral infections can be successfully treated is actually worth more than the assertion (by applicants) that some therapeutic benefit results from administration of a peptide to an animal that is not infected with a virus.

Claims 1, 2, 4, 6 are rejected under 35 U.S.C. §103 as being unpatentable over Robledo (*Am. J. Physiol.* **276** (Cell Mol Physiol 20), L229-L238, 1999).

Robledo discloses that [$Sar^9$, $MetO_2^{11}$]substance P was effective to mitigate lung injury that is induced by jet fuel.

Applicants have argued that since the reference doesn't mention ARDS or SARS, the reference is not valid. However, one of ordinary skill would have expected that at least one of the symptoms recited in claim 1, particularly alveolar membrane damage, would be ameliorated, whether caused by a virus, or by smoke inhalation.

Thus, the claims are rendered obvious.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654